

REMARKS

Before discussing the issues raised by the Examiner in the Office Action, applicant first wishes to thank the Examiner for the courtesy extended to the below signed attorney during the interview on December 17, 2002. The following remarks constitute a separate record of the substance of the interview as well as additional comments in support of the patentability of the claimed invention.

It was agreed during the interview that the present amendment overcomes the rejections of record for the reasons discussed below. However, the Examiner indicated during the interview that the amendment would not be entered because it raises a new issue requiring further consideration and/or search. Accordingly, applicant submits herewith a Request for Continued Examination so that the amendment may be entered.

In addition to the issues raised by the Examiner, it has come to applicant's attention that the proposal for amending the drawings which was filed on July 20, 2001 contains an error. In this regard it is to be noted that the Examiner has not yet acted on the aforementioned proposal for amending the drawings.

In view of the above, applicant submits herewith a second proposal for amending the drawings which supersedes the earlier proposal noted above. Accordingly, applicant hereby withdraws the earlier proposal filed on July 20, 2001, in favor of the second proposal submitted herewith.

With respect to the proposal for amending the drawings, it will be recalled that the Examiner noted in the Office Action dated April 27, 2001 that Figure 6 is improperly labeled. The Examiner required applicant to label the first page of the drawing as Figure 6A and the second, third, fourth and fifth continuing pages as

Figures 6B, 6C, 6D, and 6E respectively. However, the pages in the proposal filed on July 20, 2001, were inadvertently in the incorrect order and were thus not labeled in the appropriate sequential order as suggested by the Examiner. Accordingly, applicant submits herewith the second proposal for amending the drawings wherein the above-noted defect is corrected.

The examiner notes in item 7 on page 2 of the office action that the specification lacks antecedents or descriptive support for SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13 and SEQ ID NO: 15. Accordingly, applicant has amended the specification to provide the antecedent basis or support for the aforementioned sequence listing. With respect to the aforementioned sequences, it is to be noted that original figure 6 shows the complete *fig* gene and the deduced amino acid sequence of the encoded protein (amino acids 1-1092) and nitrogenous bases 1-3600. The sequence of figure 6 is identified in the specification as SEQ ID NO: 14.

Pages 19-21 of the application as filed, shows the nitrogenous base sequence of SEQ ID NO: 10 and a corresponding amino acid sequence (SEQ ID NO: 11) prior to the determination of a few of the amino acids and their corresponding codons. However, the undetermined amino acids and their corresponding codons (only one base of the corresponding codons is undetermined) are found in the original figure 6 which shows the entire gene and the amino acid sequence of the expressed protein from this gene. In this regard it is to be noted that all of the undetermined acids and corresponding codons on page 19-21 of the specification are located between base numbers 24 and 1766 and that the base sequence comprising bases 24-1766 on pages 19-21 corresponds to bases 255-1977 of figure 6 wherein all of the bases 255-1977 are specifically identified. Thus all of the previously unidentified bases on pages 19-21 (SEQ ID NO: 10) are identified via figure 6. Furthermore, since figure 6 identified all of the amino acids encoded by the above-noted region on pages 19-21 of the

specification, then it follows that all of the undetermined amino acids on pages 19-21 of the specification are likewise identified. Accordingly the sequence on pages 19-21 of the specification has been amended to identify all of the undetermined bases (i.e., nitrogenous base numbers 160, 173, 242, 1010 and 1177) and to identify the amino acids encoded by the codons which contain the aforementioned bases. Consequently the sequence of SEQ ID NO: 10 depicted on pages 19-21 now corresponds exactly to SEQ ID NO: 10 of the sequence listing submitted in this application pursuant to the requirements of rules 821 through 825.

Page 9 of the specification at lines 32-33 contains a reference to "the insert of pSE100" which encodes a 581 amino acid protein termed FIG. However, it is apparent that there are actually 582 amino acids in this protein because it is noted on page 10, lines 21-22, that "the insert of pSE100 contains the sequence corresponding to residue 75 to 656". Residues 75-656 define a protein containing 582 amino acids. Furthermore, amino acid residue number 656 in figure 6 is glycine. Thus, it is self-evident that the identified protein contains 582 amino acids, not 581. Accordingly, "581" on page 9, line 33, has been changed to 582.

Furthermore, since the 582nd amino acid is glycine, the corresponding protein of original claim 9 (SEQ ID NO: 13 which contains the 581 amino acids) has been amended to include glycine as amino acid number 582 and SEQ ID NO: 13 of the sequence listing has been likewise corrected to include glycine of residue number 656 as noted above.

As noted above, the "insert of pSE100" encodes 582 amino acid protein which corresponds to amino acid residues 75-656 of figure 6. Since a triplet codon is required for each of the 582 amino acids, it follows that the corresponding DNA which encodes for this protein, must have 1746 nitrogenous bases ($582 \times 3 = 1746$). The nucleotide

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sequence having the above-noted 1746 bases is also shown in figure 6 immediately above the corresponding amino acid sequence. This 1746 base sequence begins with the codon TCT which codes for the initial amino acid "S" (base numbers 255, 256 and 257 in figure 6) and ends with the codon GGA (base numbers 1998, 1999 and 2000 in figure 6) which codes for amino acid number 582 which, as discussed above, is glycine.

Upon further review of SEQ ID NO: 12 in the sequence listing, it has become apparent that the last two bases (i.e., GA) in the terminal codon "GGA" as noted above, is missing from SEQ ID NO: 12, but should be present since the codon for amino acid number 582 is GGA for the reasons discussed above. In other words the bases "GA" should be added to the end of the 1744 base sequence of SEQ ID NO:12 so that the sequence includes 1746 bases with the complete terminal codon "GGA". Accordingly SEQ ID NO: 12 has been corrected in the revised sequence listing submitted herewith to include 1746 bases, including the complete codon "GGA" which codes for glycine at amino acid location number 582. A similar change has been made to claim 8 since claim 8 recites SEQ ID NO: 12.

In view of the above discussed changes to the substitute sequence listing submitted herewith, the below signed attorney hereby states that the application, as filed, supports the substitute sequence listings submitted herewith and said substitute sequence listings include no new matter. The below signed attorney hereby also states that the content of the substitute paper and substitute computer readable copies of the sequence listings submitted herewith are the same.

The examiner has rejected claims 1 and 25 under 35 U.S.C. § 102(b) as being anticipated by DE 3583987 A1. In addition the examiner has rejected claims 1 and 25 under 35 U.S.C. § 102(b) as being anticipated by Fiedler et al. The examiner has

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maintained these rejections because the rejected claims do not define the polypeptide structurally and does not exclude epidermidin. In this regard the examiner notes that the claimed protein is not identified by one or more structural limitations and it therefore encompasses epidermidin or any other purified protein of *Staphylococcus epidermidis*.

In response to these rejections, claims 1 and 25 have been amended so that the claimed proteins are limited to the proteins of SEQ ID NO: 15 and SEQ ID NO: 13. Thus, the claims now recite the required structural limitations to distinguish the invention over the cited references.

The examiner has rejected claims 1 and 25 under 35 U.S.C. § 102(e) as being anticipated by Katz et al. or Alborn et al. Once again, in rejecting the claims the examiner urges that the claimed protein is not identified by one or more structural limitations and it therefore is broad enough to encompass the protein disclosed by the two cited references. Obviously this rejection is no longer available to the amended claims since the claims have been amended to limit the protein to the proteins of SEQ ID NO: 15 and SEQ ID NO: 13.

The examiner has rejected claims 25, 30 and 32 under 35 U.S.C. § 112, second paragraph, as being indefinite. In rejecting the claims the examiner urges that the phrase "having fibrinogen binding activity" in line 2 of claim 25 and claim 30 should be deleted because this recitation is already encompassed by claim 1. Accordingly, the above-noted recitation has been deleted from claims 25 and 30. Accordingly, it is believed that the claims are now in full compliance with 35 U.S.C. § 112, second paragraph.

The examiner has rejected claims 1, 25 and 30-32 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In rejecting the claims the examiner urges that there is no descriptive support in the originally filed specification for the phrase "polypeptide fragment of the protein having fibrinogen binding activity". More particularly, the examiner urges that there is no support for "polypeptide fragment" and for such a fragment "having fibrinogen binding activity". Applicant submits that this rejection is no longer appropriate since the phrase "fragment of the protein having fibrinogen binding activity" has been deleted from the claims and, furthermore, the claims more particularly recite that the protein is SEQ ID NO: 15 or SEQ ID NO: 13.

The examiner has rejected claims 1, 25 and 31 under 35 U.S.C. § 102(b) as being anticipated by McDevitt et al. In rejecting the claims the examiner urges that the protein fragments encompassed by the rejected claims reads on the proteins disclosed by the cited reference. Applicant submits that this rejection is no longer appropriate in view of the above-discussed amendments to the claims. In particular, such fragments are no longer encompassed by the claims undergoing examination.

Lastly, the examiner has rejected claims 1 and 30 under 35 U.S.C. § 103(a) as being unpatentable over Fiedler et al. or McDevitt et al. in view of Marston et al. In rejecting the claims the examiner notes that the expression of a polypeptide or fragment thereof as a fusion polypeptide is well known and is broad enough to cover the fusion proteins suggested by the combined teachings of the cited references. Applicant submits that the more particular proteins encompassed by the amended claims overcomes this rejection since none of the prior art references, either alone or in

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combination, disclose or suggest the protein of SEQ ID NO: 15 or SEQ ID NO: 13, let alone the fusion proteins obtained from these particular proteins.

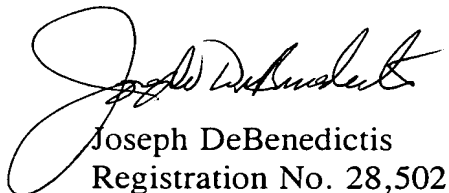
In view of the above arguments and further amendment to the claims and specification, applicant respectfully requests reconsideration and allowance of all the claims which are currently pending in the application.

Attached hereto is a marked-up version of changes made to the application by this amendment. The attachment is captioned "Version with Markings to Show Changes Made".

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The paragraph beginning on page 9, line 24, and ending on page 10, line 5, has been changed as follows:

Example 3: DNA sequencing and sequence analysis

Eight colonies coming from the second panning (pH 3.4) against fibrinogen described in Example 2 were chosen for further studies. Phagemid DNA from these colonies was prepared and partially sequenced. Seven of the clones seemed to contain the same insert. One of these seven clones called pSE100 was chosen for further studies. Purified phagemid DNA from the clone pSE100 was analysed by restriction mapping which revealed that the phagemid contained an insert of ~ 1.8 kilo base pair (kb). The nucleotide (nt) sequences of the complete inserts of pSE100 were determined and the nt and deduced amino acid (aa) sequences were analysed using the PC-gene program. This analysis revealed that the insert of pSE100 contains an open reading frame of 1.745 nt (sequence list). Thus the insert encodes a [581] 582 aa protein, termed protein FIG (and the corresponding gene termed *fig*), with a calculated molecular mass of -65 kDa (sequence list). Furthermore, the sequence analysis show that the insert of pSE100 is in the correct reading frame with the vector sequences in the 5'-and 3'-ends. This means that the insert gives rise to a fusion with the *pel* leader and the *myc* tail (sequence list) and that the native 5'- and 3'-ends of the *fig* gene is not present in the pSE100 clone.

The paragraph beginning with the term "Sequence list" on page 19, line 1 and ending with the last line of text on page 21, has been changed as follows:

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Sequence list (SEQ ID NO: 10)

10 20 30 40 50 60 70
ACCACCACCACCACCACCACCCCTCTAGTGATGAAGAAAGAATGATGTGATCAATAATAATCAGTCAATAA
H H H H H H P S S D E E K N D V I N N N Q S I
← *Pel Leader*

80 90 100 110 120 130 140
ACACCGACGATAATAACCAAATAATTAAAAAGAAGAAACGAATAACTACGATGGCATAGAAAAACGCTCAG
N T D D N N Q I I K K E E T N N Y D G I E K R S

150 160 170 180 190 200 210
AAGATAGAACAGACTC~~X~~ACAACAATGT~~X~~GATGAAACGAAGCAACATTTTACAAAAGACCCCTCAAGATA
E D R T E ~~X~~ T T N ~~X~~ D E N E A T F L Q K T P Q D
replace N with A
replace N with A
replace x with S
replace x with V
replace N with A

220 230 240 250 260 270 280
ATACTCATCTTACAGAAGAAGAGGT~~X~~AAAGAATCCTCATCAGTCGAATCCTCAAATTCATCAATTGATACTG
N T H L T E E E ~~X~~ K E S S S V E S S N S S I D T
replace x with V

290 300 310 320 330 340 350 360
CCCAACAACCATCTCACACAACAATAAATAGAGAAGAATCTGTTCAAACAAGTGATAATGTAGAAGATTCAC
A Q Q P S H T T I N R E E S V Q T S D N V E D S

370 380 390 400 410 420 430
ACGTATCAGATTTTGCTAACTCTAAAATAAAAGAGAGTAACACTGAATCTGGTAAAGAAGAGAATACTATAG
H V S D F A N S K I K E S N T E S G K E E N T I

440 450 460 470 480 490 500
AGCAACCTAATAAAGTAAAGAAGATTCAACAACAAGTCAGCCGTCTGGCTATACAAATATAGATGAAAAA
E Q P N K V K E D S T T S Q P S G Y T N I D E K

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Sequence list cont.

510 520 530 540 550 560 570
TTTCAAATCAAGATGAGTTATTAAATTTACCAATAATGAATATGAAAATAAGGCTAGACCATTATCTACAA
I S N Q D E L L N L P I N E Y E N K A R P L S T

580 590 600 610 620 630 640
CATCTGCCCAACCATCGATTAAACGTGTAACCGTAATCAATTAGCGGCGGAACAAGGTTCTGAATGTTAACC
T S A Q P S I K R V T V N Q L A A E Q G S N V N

650 660 670 680 690 700 710 720
ATTTAATTAAAGTTACTGATCAAAGTATTACTGAAGGATATGATGATAGTGAAGGTGTTATTAAAGCACATG
H L I K V T D Q S I T E G Y D D S E G V I K A H

730 740 750 760 770 780 790
ATGCTGAAAACCTTAATCTATGATGTAACCTTTTGAAGTAGATGATAAGGTGAAATCTGGTGATACGATGACAG
D A E N L I Y D V T F E V D D K V K S G D T M T

800 810 820 830 840 850 860
TGGATATAGATAAGAATACAGTTCATCAGATTTAACCGATAGCTTTACAATACCAAAAATAAAGATAATT
V D I D K N T V P S D L T D S F T I P K I K D N

870 880 890 900 910 920 930
CTGGAGAAATCATCGCTACAGGTACTTATGATAACAAAAATAAACAAATCACCTTACTTTTACAGATTATG
S G E I I A T G T Y D N K N K Q I T Y T F T D Y

940 950 960 970 980 990 1000
TAGATAAGTATGAAAATATTAAAGCACACCTTAAATTAACGTGATACATTGATAAATCAAAGGTTCCAAATA
V D K Y E N I K A H L K L T S Y I D K S K V P N

1010 1020 1030 1040 1050 1060 1070 1080
ATAATACCAAGTTAGATGTAGAATATAAAACGGCCCTTTCATCAGTAAATAAACAATTACGGTTGAATATC
N N T K L D V E Y K T A L S S V N K T I T V E Y

1090 1100 1110 1120 1130 1140 1150
AAAGACCTAACGAAAATCGGACTGCTAACHTTCAAAGTATGTTTACAAATATAGATACGAAAAATCATACAG
Q R P N E N R T A N X Q S M F T N I D T K N H T
replace N with C
replace x with L

1160 1170 1180 1190 1200 1210 1220
TTGAGCAAACGATTATATTAAACCTCTTCGTTATTCAGCCAAGGAACAAATGTAAATATTTTCAGGGAATG
V E Q T I Y I N X L R Y S A K E T N V N I S G N
replace x with P

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Sequence list cont.

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1230      1240      1250      1260      1270      1280      1290
|         |         |         |         |         |         |
GTGATGAAGGTTCAACAATTATAGACGATAGCACAAATAATTAAAGTTTATAAGGTTGGAGATAATCAAAATT
G D E G S T I I D D S T I I K V Y K V G D N Q N

1300      1310      1320      1330      1340      1350      1360
|         |         |         |         |         |         |
TACCAGATAGTAACAGAATTTATGATTACAGTGAATATGAAGATGTCACAAATGATGATTATGCCCAATTAG
L P D S N R I Y D Y S E Y E D V T N D D Y A Q L

1370      1380      1390      1400      1410      1420      1430      1440
|         |         |         |         |         |         |         |
GAAATAATAATGATGTGAATATTAATTTGGTAATATAGATTACCATATATTATTAAAGTTATTAGTAAAT
G N N N D V N I N F G N I D S P Y I I K V I S K

1450      1460      1470      1480      1490      1500      1510
|         |         |         |         |         |         |
ATGACCTAATAAGGATGATTACAGCACTATACAGCAAATCTGTGACAATGCAGACGACTATAAATGAGTATA
Y D X N K D D Y T T I Q Q T V T M Q T T I N E Y
    ^
    |
    | replace N with C
    |
    | replace x with P

1520      1530      1540      1550      1560      1570      1580
|         |         |         |         |         |         |
CTGGTGAGTTTAGAACAGCATCCTATGATAATACAATTGCTTTCTCTACAAGTTCAGGTCAAGGACAAGGTG
T G E F R T A S Y D N T I A F S T S S G Q G Q G

1590      1600      1610      1620      1630      1640      1650
|         |         |         |         |         |         |
ACTTGCCTCCTGAAAAAAGTTATAAAATCGGAGATTACGTATGGGAAGATGTAGATAAAGATGGTATTCAA
D L P P E K T Y K I G D Y V W E D V D K D G I Q

1660      1670      1680      1690      1700      1710      1720
|         |         |         |         |         |         |
ATACAAATGATAATGAAAAACCGCTTAGTAATGTATTGGTAACCTTGACGTATCCTGATGGAAGTTCAAAT
N T N D N E K P L S N V L V T L T Y P D G T S K

1730      1740      1750      1760      1770      1780
|         |         |         |         |         |
CAGTCAGAACAGATGAAGATGGGAAATATCAATTTGATGGGGTGCAGGTTCGAC
S V R T D E D G K Y Q F D G V Q V D
                                >
                                Hyc tail

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Sequence list. A partial nucleotide sequence of the putative *fig* gene from *S. epidermidis* strain HB and the deduced amino acid sequence. The vector sequences in the junction of the 5'- and 3'-ends are indicated.

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IN THE CLAIMS:

The below claims were revised as follows:

1. (Six times amended) A purified *Staphylococcus epidermidis* protein [or polypeptide fragment of the protein having fibrinogen binding activity] having the amino acid sequence of SEQ ID NO: 15, or a polypeptide having fibrinogen binding activity and having the amino acid sequence of SEQ ID NO: 13.

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8. (Twice amended) Recombinant DNA molecule according to claim 2, wherein said DNA molecule contains SEQ ID NO:12 which is:

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1   TCTAGTGATGAAGAAAAGAATGATGTGATCAATAATAATCAGTCAATAAA
51  CACCGACGATAATAACCAAATAATTAAAAAAGAAGAAACGAATAACTACG
101 ATGGCATAGAAAAACGCTCAGAAGATAGAACAGAGTCAACAACAAATGTA
151 GATGAAAACGAAGCAACATTTTTACAAAAGACCCCTCAAGATAATACTCA
201 TCTTACAGAAGAAGAGGTAAAAGAATCCTCATCAGTCGAATCCTCAAATT
251 CATCAATTGATACTGCCCAACAACCATCTCACACAACAATAAATAGAGAA
301 GAATCTGTTCAAACAAGTGATAATGTAGAAGATTACACGTATCAGATTT
351 TGCTAACTCTAAAATAAAAGAGAGTAACACTGAATCTGGTAAAGAAGAGA
401 ATACTATAGAGCAACCTAATAAAGTAAAAGAAGATTCAACAACAAGTCAG
451 CCGTCTGGCTATACAAATATAGATGAAAAAATTTCAAATCAAGATGAGTT
501 ATTAAATTTACCAATAAATGAATATGAAAATAAGGCTAGACCATTATCTA
551 CAACATCTGCCCAACCATCGATTAAACGTGTAACCGTAAATCAATTAGCG
601 GCGGAACAAGGTTTGAATGTTAACCATTTAATTAAAGTTACTGATCAAAG
651 TATTACTGAAGGATATGATGATAGTGAAGGTGTTATTAAAGCACATGATG
701 CTGAAAACCTTAATCTATGATGTAACTTTTGAAGTAGATGATAAGGTGAAA
751 TCTGGTGATACGATGACAGTGGATATAGATAAGAATACAGTTCCATCAGA
801 TTTAACCGATAGCTTTACAATACCAAAAATAAAAAGATAATTCTGGAGAAA
851 TCATCGCTACAGGTACTTATGATAACAAAAATAAACAAATCACCTATACT
901 TTTACAGATTATGTAGATAAGTATGAAAATATTAAAGCACACCTTAAATT
951 AACGTCATACATTGATAAATCAAAGGTTCCAAATAATAATACCAAGTTAG
1001 ATGTAGAATATAAAACGGCCCTTTTCATCAGTAAATAAAACAATTACGGTT
1051 GAATATCAAAGACCTAACGAAAATCGGACTGCTAACCTTCAAAGTATGTT
1101 TACAAATATAGATACGAAAAATCATAACAGTTGAGCAAACGATTTATATTA
1151 ACCCTCTTCGTTATTCAGCCAAGGAAACAAATGTAAATATTTTCAGGGAAT
1201 GGTGATGAAGGTTCAACAATTATAGACGATAGCACATAATTAAAGTTTA
1251 TAAGGTTGGAGATAATCAAAATTTACCAGATAGTAACAGAATTTATGATT
1301 ACAGTGAATATGAAGATGTCACAAATGATGATTATGCCCAATTAGGAAAT
1351 AATAATGATGTGAATATTAATTTTGGTAATATAGATTCACCATATATTAT
1401 TAAAGTTATTAGTAAATATGACCCTAATAAGGATGATTACACGACTATAC
1451 AGCAAACCTGTGACAATGCAGACGACTATAAATGAGTATACTGGTGAGTTT
1501 AGAACAGCATCCTATGATAATACAATTGCTTTCTCTACAAGTTCAGGTCA
1551 AGGACAAGGTGACTTGCCTCCTGAAAAAATTTATAAAATCGGAGATTACG
1601 TATGGGAAGATGTAGATAAAGATGGTATTCAAATAACAATGATAATGAA
1651 AAACCGCTTAGTAATGTATTGGTAAGTTTGACGTATCCTGATGGAACTTC
1701 AAAATCAGTCAGAACAGATGAAGATGGGAAATATCAATTTGATGGA
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or homologues thereof.

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9. (Twice amended) Recombinant DNA molecule according to claim 2, wherein said DNA molecule encodes amino acid sequence of SEQ ID NO: 13 which is:

1 SSDEEKNDVINNNQSINTDDNNQIIKKEET
31 NNYDGLIEKRSEDRTESTTNVDENEATFLQK
61 TPQDNTHLTEEEVKESSSVESSNSSIDTAQ
91 QPSHTTINREESVQTSDNVEDSHVSDFANS
121 KIKESNTESGKEENTIEQPNKVKEDSTTSQ
151 PSGYTNIDEKISNQDELLNLPINEYENKAR
181 PLSTTSAQPSIKRVTVNQLAAEQGSNVNHL
211 IKVTDQSITEGYDDSEGVKAHDAENLIYD
241 VTFEVDDKVKSGDTMTVDIDKNTVPSDLTD
271 SFTIPKIKDNSGEIIATGTYDNKNKQITYT
301 FTDYVDKYENIKAHLKLTSYIDKSKVPNNN
331 TKLDVEYKTALSSVNKTITVEYQRPNENRT
361 ANLQSMFTNIDTKNHTVEQTIYINPLRYSA
391 KETNVNISGNGDEGSTIIDDSTIIKVYKVG
421 DNQNLPSNRIYDYSEYEDVTNDDYAQLGN
451 NNDVNINFGNIDSPYIIKVISKYDPNKDDY
481 TTIQQTVTMQTTINEYTGEFRTASYDNTIA
511 FSTSSGQGQGDLPPEKTYKIGDYVWEDVDK
541 DGIQNTNDNEKPLSNVLVTLTYPDGTSKSV
571 RTDEDGKYQFDG

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25. (Four times amended) A vaccine composition including the protein or polypeptide [fragment of the protein having fibrinogen binding activity] according to claim 1.

30. (Amended) A fusion protein comprising the protein or polypeptide [fragment of the protein having fibrinogen binding activity] according to claim 1.